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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,544	05/26/2006	Catherine Picart	BJS-3608-8	3195
23117 7590 11/05/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER SELLMAN, CACHET I	
			ART UNIT 1715	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,544	<b>Applicant(s)</b> PICART ET AL.	
	<b>Examiner</b> CACHET I. SELLMAN	<b>Art Unit</b> 1715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-51, 53-65 and 67-72 is/are pending in the application.
- 4a) Of the above claim(s) 51, 54-65 and 67-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-50 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/26/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 37-53 and species a (claims 37-50 and 53) in the reply filed on 8/30/2010 is acknowledged. The traversal is on the ground(s) that the prior art cited in the lack of unity does not have the special technical features of the amended claims. This is not found persuasive because such a technical feature was known in the prior art. Qiu et al. (US 2003/0143335) teaches forming layers of a polycationic and polyanionic onto a substrate in the presence of N-hydroxysulfosuccinimide to perform coupling reaction between amino groups and carboxylate groups to form an amide bond (paragraph 0400).

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

2. Claim 44 is objected to because of the following informalities: the claim states "...polymethacrylic acid, acid..." The Examiner believes the addition of the word "acid" is an error and should be removed.

3. Claim 46 contains a typographical error; the word "oxyde" should read "oxide" in line 5.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 38, 41, and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

a. In the present instance, claim 38 recites the broad recitation "any complementary interaction" and the claim also recites "especially electrostatic attraction and hydrogen bridging" which is the narrower statement of the range/limitation.

b. In the present instance, claim 41 recites the broad recitation "number of said layer pairs is from 1 to 1000" and the claim also recites "preferably from 2 to

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100, more preferably from 5 to 60" which is the narrower statement of the range/limitation.

Claims 44 and 45 have improper Markush group, the claims states "are selected in the group consisting of," the claims should state "are selected **from** the group consisting of."

Claim 44 states "...polyuronic acid (alginic, galacturonic, glucuronic...), glycosaminoglycans (hyaluronic acid, dermatan sulphate, chondroitin sulphate, heparin, heparin sulphate, and keratin sulphate), poly(D,L-aspartic acid)... "The inclusion of the terms in parenthesis renders the claim indefinite because it is unclear whether the limitation(s) following the parenthesis are part of the claimed invention.

Claim 45 states "...poly(mannoseamine, and other sugars)..." The inclusion of the term and other sugars renders the claim indefinite because it is unclear whether the term "and other sugars" is part of the claimed invention.

Claim 45 recites the limitation "the polyamino acids" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 46 states "...can further comprise polymers with different functional groups, including cationic (sulfonium, phosphonium, ammonium, hydroxyamine, hydrazide), anionic (including poly(styrene sulfonate), poly(phosphate), polynucleic acid...) and neutral (including polyacrylamide, polyethylene oxide, polyvinyl alcohol) polymers. It is unclear to the Examiner whether the limitations following "including" are part of the claimed invention.

Claim 47 states "... comprise a variety of materials, preferably synthetic polyions (polymers presenting ions), biopolymer **such as** DNA, RNA, collagen, peptides (**such as** a RGD sequence, Melanoma stimulating hormone, or burforin), proteins, and enzymes, cells, viruses, dendrimers, colloids, inorganic and organic particles, dyes, vesicles, nano(or micro) capsules, nano(or micro) particles, polyelectrolytes complexes, free or complex drugs, cyclodextrins, and mixtures thereof," it is unclear as to what is being claimed. The claim lists a broad range of "a variety of materials" and then lists preferred materials; it is unclear if the preferred materials are part of the claimed invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 37-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Qiu et al. (US 2003/01433335).

As to claim 37, Qiu et al. discloses a process of coating contact lenses with a multilayer of polyelectrolytes of polyacrylic acid (supplies carboxylic groups) and poly(allyl amine hydrochloride) (supplied amino groups, see paragraph 0014) by dipping the contact into a solution of each polyelectrolyte, the contact lens is then activated by soaking the coated lenses into a solution of 1-(3-dimethylaminopropyl)-3-

ethylcarbodiimide hydrochloride) (EDC, coupling agent) and sulfo-N-hydroxysuccinimide (NHS) (see Example K paragraph 0400).

As to claim 38, the multilayers are assembled via electrostatic attraction (see 0012-0013).

As to claim 39, the layers are biocompatible (i.e. they are used on contact lenses).

As to claim 40, the multilayer comprises at least one pair of cationic polyelectrolytes (PAH) and anionic polyelectrolyte (PAA).

As to claim 41, the multilayer comprises 4 pairs (see 0400).

As to claim 42, the amino groups and carboxylic groups are attached by covalent bonds (see paragraph 0205).

As to claims 43-45, the cationic polyelectrolyte (PAH) supplies the amino groups and the anionic polyelectrolyte (PAA) supplies the carboxylic groups.

As to claim 46, the multilayers can further comprise polymers with different functional groups (see paragraph 0107).

As to claim 47, the multilayers can comprise a variety of materials such as dyes, bioactive agents (see 016-168).

As to claim 48-50, the coupling agent is EDC.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qiu et al. as applied to claim 37 above in view of Lennon et al. (US 5721361).

The teachings of Qiu et al. as applied to claim 37 are as stated above.

Qiu et al. fail to teach the use of N-hydroxysulfosuccinimide para-nitrophenol with the coupling agent as required by claim 37.

Qiu et al. does teach the use of N-hydroxysulfosuccinimide with the coupling agent.

However, Lennon et al. discloses coupling agents which are capable of coupling a carboxylic acid group with a terminal amine group to form an amide bond between the two materials. Lennon et al. discloses various types of coupling agents such as NHS which can be used in conjunction with a coupling agent from another group such as EDC and p-nitrophenol (see col. 16, line 65 - col. 17, line 51).

It would have been obvious to one having ordinary skill in the art to use the NHS-para nitrophenol with the coupling agent of Qiu et al. through routine experimentation especially since Lennon et al. teaches such agents are capable of forming an amide bond between carboxylic and amine groups which is desired in Qiu et al. also, especially since simple substitution of one known element for another would have predictable results.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.



Suzuki et al. "Modification of Polyelectrolyte layered assembly using an active ester of azobenzene carboxylate."

Staros et al. "Enhancement of N-hydroxysulfosuccinimide of water soluble carbodiimide mediated coupling reactions."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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